

REMARKS

Before addressing the objections raised by the examiner, we wish to bring to his attention the lack of any reference or reply to our reasonably stated request, repeated here in quotes. It would be polite if this was addressed in any future reply as well as prior modifications/arguments at least acknowledged.

“Before that, applicant desires to have examiner acknowledge the statements below reflecting the true status of this case prior to assignment to him. In particular supervisory patent examiner Jose Dees and applicant’s attorney had an in-person interview which included his suggestion as to an amendment to claim 1 to obtain allowance. Response to his suggestion led to the amendments submitted on June 6, 2003. It would seem after complying with the suggestion of the supervisory examiner, rather than allowance, the file is being reopened for new examination. We would like a formal answer as to how this is a reasonable progression in the prosecution of this case.”

In reply to specific § 112 objections, claim 10 has been modified to remove ‘and their derivatives’ and claim 12 has been cancelled in agreement with examiner’s suggestions. In claim 11, while the point made about derivatives makes sense, there are known molecules which must change to become photosensitizers rather than merely photo-absorbers, i.e. they do not sensitize the reaction in their original form, but first must change their structure before being able to photosensitize a reaction. The derivatives term is dropped, but we wish to retain the precursor language, because in the PDT field, these are understood as different from photosensitizers. As to the questions related to claim 16 and by deduction 17-19, we address the last here and the others below. Claim 19 is amended to more correctly identify the primary swelling action which is restricted by the application of a cover, which envisioned to be more than a band-aid, because evaporation nor protection from casual infection are not the reasons for covering the treated area.

In reply to the more general § 112 and 102 objections, the reply begins with a restatement of the novel aspects of the invention and as reflected in amended claims 1, new claims 21-4, and previously presented claims. The invention is the new combination of

swellable compositions and compounds/drugs to introduce the drugs through 'intact skin', stratum corneum, without the use of needles, needle patches or other direct attack to span the stratum corneum. After removal of hair from hair follicles, or in diseases where hair loss occurs the hair follicles generally close or collapse due to stress from the collagen and elastic fibers of the dermis. (specification page 10, lines 11-17). The primary aim as given in the specification (page 5, lines 25ff), is to open or maintain open hair follicles to maintain passages for the introduction/penetration of compounds/drugs, including photosensitizing molecules for photodynamic therapy. The use of swellable compositions, which are safe to use with humans, {known in cosmetics and topical drugs} to open and maintain open a hair follicle (amended claim 1 lines 8-9) is not discussed in the prior patents of the inventor nor in the prior art presented by examiner. To emphasize this the basic independent claim, claim 1, has been restricted to cases where there is no longer hair in the hair follicle when the combination formulation is applied to the area containing the 'empty' hair follicles. The present invention is not a hair removal method, it is a method to make use of empty hair follicles to enhance the introduction of compounds/drugs through intact skin (stratum corneum). Thus there is no double patenting, as the claims are patentably distinct in contrast to the examiner's comments because the volume swelling coming from the addition of swellable compositions with the drugs is not anticipated nor made obvious by US 6,287,549.

Furthermore as to the adding the art of Li et al.; US 5,914,126 deals with delivering materials into a hair follicle to be able to treat/kill the remnant follicle structure. The present invention includes in its action not only delivery, but also the restoration of the barrier properties and the diffusion of the compounds/drugs into the dermis and beyond through the blood system (specification, page 11, lines 7-10). The new claims 21-24 attempt to more clearly capture this portion of the invention.

On the basis of delineation and differentiation of the basic claims, especially claim 1, in reply to the examiner's objections, the other §102 and 103 objections are to dependent claims whose novelty and non-obviousness stem from the independent claim.

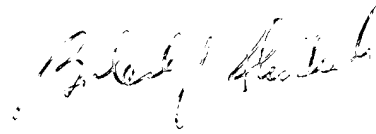
With these changes and remarks it is believed that the disclosure is now in condition for allowance. Reconsideration is respectfully requested. An early and favorable response is

earnestly solicited. If necessary, a telephone call would be appreciated to discuss any further final changes to be made to render the claims allowable. Thank you.

Respectfully submitted,

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CeramOptec Industries, Inc.
515 Shaker Road
East Longmeadow, MA 01028
Phone: (413) 525-8222

A handwritten signature in black ink, appearing to read "Bolesh J. Skutnik", is written over the typed name.

Bolesh J. Skutnik, PhD, JD
Reg. No. 36,347
Attorney for Applicants

Fax: (413) 525-0611